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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TOTH, KAREN E	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
06/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,297	BRODNICK ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-12,18,19,24 and 25* is/are allowed.

6)☒ Claim(s) *13-17, 20-23, 26-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The oath currently states "material to the examination", whereas the necessary phrase is "material to patentability".

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Kearns (US Patent 4387722).

Kearns discloses a patient monitor comprising a plurality of inputs configured to receive signals from electrodes attached to the patient (column 7, lines 52-65; column 8, lines 12-19; column 13, lines 29-31, 39-42, 45-48; column 14, lines 29-39); a processing

circuit configured to process the signals to generate a respiration parameter relating to the patient's respiration (elements 300, 400); and a display that is configured to display the respiration parameter and display an indication of abdominal respiration (column 10, lines 55-62; column 28, lines 59-61; figure 6j).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 13-17, 20-22, and 26-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Kearns in view of Rohde (US Patent 5876351).

Regarding claim 13, Kearns discloses an apparatus comprising first and second input electrodes attached to opposite sides of a patient's thorax (column 7, lines 52-65; column 8, lines 12-19; column 13, lines 29-31, 39-42); and a third input electrode

configured to eliminate or reduce a common mode voltage in signals from the first and second electrodes (column 13, lines 45-48; column 14, lines 29-39); and a processing circuit configured to detect fluctuations in impedance in the conductive path between the first and second electrodes and use them to derive a respiration signal (elements 300, 400). Kearns does not disclose the third electrode being attached to the patient's right leg.

Rohde teaches a monitoring apparatus comprising input electrodes and a common mode electrode used to eliminate common mode voltage from the inputs, where the common mode electrode is attached to the patient's right leg (column 7 line 55 to column 8 line 5), in order to ensure an accurate common mode measurement. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have placed the reference electrode of Kearns' apparatus on the patient's leg, as taught by Rohde, in order to obtain an accurate reference signal.

Regarding claim 14, Kearns further discloses using the same components of the apparatus to monitor the patient's electrocardiogram (ECG) (column 7, lines 54-56; column 14 line 52 to column 15 line 45; column 35, line 21 to column 36 line 23).

Regarding claims 15 and 16, Rohde further discloses that one of the measuring electrodes may be connected to the patient's left leg (column 7, lines 29-37), since that location is well-known in the art as being one option for monitoring a patient's condition using electrodes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the apparatus of Kearns in view of Rohde, which inherently includes connections between the electrodes and the processing circuit

so that the signals from the electrodes may be processed, and placed a first electrode on the patient's left leg, as taught by Rohde, since that location is well-known in the art.

Regarding claim 17, Kearns further discloses that the second electrode may be placed below the patient's armpit (since the 6th intercostals space is below the armpit – column 13, lines 29-31); the processing circuit is inherently connected to the electrode, in order to process signals from it.

Regarding claims 20-22, Kearns further discloses an electronic display and that the processing circuit is configured to display the respiration signal as a respiration rate or trace (column 10, lines 55-62; column 28, lines 59-61; figure 6j).

Regarding claim 26, Kearns discloses a system comprising first and second means for measuring impedance attached to opposite sides of a patient's thorax (column 7, lines 52-65; column 8, lines 12-19; column 13, lines 29-31 and 39-42); a third means for measuring impedance for eliminating or reducing a common mode voltage present in signals obtained from the first and second means (column 13, lines 45-48; column 14, lines 29-39); and a means for monitoring respiration configured to detect fluctuations in impedance between the first and second means, and to derive a respiration signal from the fluctuations, where the monitoring means is coupled to the first and second sensing means (elements 300, 400). Kearns does not teach the common mode elimination means being placed on the patient's right leg.

Rohde teaches a monitoring system comprising input electrodes and a common mode electrode used to eliminate common mode voltage from the inputs, where the common mode electrode is attached to the patient's right leg (column 7 line 55 to

column 8 line 5), in order to ensure an accurate common mode measurement. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have placed the reference electrode of Kearns' system on the patient's leg, as taught by Rohde, in order to obtain an accurate reference signal.

Regarding claim 27, Kearns further discloses using the same means to also monitor ECG (column 7, lines 54-56; column 14 line 52 to column 15 line 45).

Regarding claims 28 and 29, Rohde further discloses that one of the means for sensing may be connected to the patient's left leg (column 7, lines 29-37), since that location is well-known in the art as being one option for monitoring a patient's condition using electrodes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Kearns in view of Rohde, which inherently includes connections between the electrodes and the processing circuit so that the signals from the electrodes may be processed, and placed a first electrode on the patient's left leg, as taught by Rohde, since that location is well-known in the art.

Regarding claim 30, Kearns further discloses that the second means for sensing may be placed below the patient's armpit (since the 6^{th} intercostals space is below the armpit – column 13, lines 29-31); the processing circuit is inherently connected to the means for sensing, in order to process signals from it.

Regarding claims 31 and 32, Kearns further discloses that the second means for sensing may be placed at V6 or V6R (column 13, lines 29-31); the processing circuit is inherently connected to the means for sensing, in order to process signals from it.

Regarding claims 33-35, Kearns further discloses an electronic display and that the processing circuit is configured to display the respiration signal as a respiration rate or trace (column 10, lines 55-62; column 28, lines 59-61; figure 6j).

Regarding claim 36, Rohde further discloses transmitting information from the system to a hospital information system (column 6, lines 49-51), in order to allow the data to be stored outside the system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Kearns in view of Rohde with the system coupled to a hospital information system, as taught by Rohde, in order to allow collected data to be stored outside the system.

Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the structure of claims 1-12, 18, 19, and 25, including, *inter-alia*, a system having three electrodes that may be used to monitor a respiration parameter by measuring impedance between the first and second electrodes, using the third to eliminate a common mode voltage, or by measuring the impedance between the third electrode and either of the first or second electrodes.

Kearns discloses an invention having a similar structure but is only capable of monitoring by using the third electrode to eliminate common mode voltage. Belalcazar (US Patent Application Publication 2004/0102712) discloses a similar system having

three electrodes, where impedance is measured between the third electrode and each of the first and second electrodes, and the resulting impedances (3 to 1, and 3 to 2) are compared to eliminate a common mode voltage. Alkawwas (US Patent Application Publication 2002/0045836) discloses a similar invention that is used to monitor a patient's ECG. Harry (US Patent Application Publication 2002/0099277) discloses a similar system having three electrodes, but only compares impedances between any two of the electrodes. Rantala (US Patent 6553250) also discloses a similar system capable of operating in multiple modes using a plurality of electrodes and a common mode electrode, but does not disclose the specific operating modes claimed here.

The prior art of record fails to anticipate or make obvious the structure of claim 24, including, *inter-alia*, a monitoring system using electrodes to monitor a patient's respiration, where the electrode inputs generate, among other signals, an abdominal respiration signal, and the system further comprises a display that may display a parameter associated with the abdominal respiration signal.

Bornn (US Patent 5353793) discloses a system having electrodes on the patient's thorax and abdomen, but does not disclose using signals from the electrodes to monitor abdominal breathing; rather, Bornn discloses using piezoelectric transducers to monitor abdominal breathing, and using the electrodes to monitor the patient's ECG. Ricks (US Patent 4784162) discloses a system having electrodes and capable of monitoring abdominal breathing, but the electrodes are used to monitor the patient's ECG and the abdominal breathing measurements are taken using piezoelectric sensors.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4630614 to Atlas, which discloses a similar invention.

US Patent 5824029 to Weijand, which discloses a similar invention.

US Patent 5353788 to Miles, which discloses a similar invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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